

§ 864.4400

(c) *Date of 510(k), or date of PMA or notice of completion of a product development protocol is required.* (1) Preamendments ASR's; No effective date has been established for the requirement for premarket approval for the device described in paragraph (b)(3) of this section. See § 864.3.

(2) For postamendments ASR's; November 23, 1998.

(d) *Restrictions.* Restrictions on the sale, distribution and use of ASR's are set forth in § 809.30 of this chapter.

[62 FR 62260, Nov. 21, 1997]

§ 864.4400 Enzyme preparations.

(a) *Identification.* Enzyme preparations are products that are used in the histopathology laboratory for the following purposes:

(1) To disaggregate tissues and cells already in established cultures for preparation into subsequent cultures (e.g., trypsin);

(2) To disaggregate fluid specimens for cytological examination (e.g., papain for gastric lavage or trypsin for sputum liquefaction);

(3) To aid in the selective staining of tissue specimens (e.g., diastase for glycogen determination).

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60592, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989; 66 FR 38789, July 25, 2001]

Subpart F—Automated and Semi-Automated Hematology Devices

§ 864.5200 Automated cell counter.

(a) *Identification.* An automated cell counter is a fully-automated or semi-automated device used to count red blood cells, white blood cells, or blood platelets using a sample of the patient's peripheral blood (blood circulating in one of the body's extremities, such as the arm). These devices may also measure hemoglobin or hematocrit and may also calculate or measure one or more of the red cell indices (the erythrocyte mean corpuscular volume, the mean corpuscular hemoglobin, or the mean corpuscular hemoglobin con-

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centration). These devices may use either an electronic particle counting method or an optical counting method.

(b) *Classification.* Class II (performance standards).

[45 FR 60593, Sept. 12, 1980]

§ 864.5220 Automated differential cell counter.

(a) *Identification.* An automated differential cell counter is a device used to identify one or more of the formed elements of the blood. The device may also have the capability to flag, count, or classify immature or abnormal hematopoietic cells of the blood, bone marrow, or other body fluids. These devices may combine an electronic particle counting method, optical method, or a flow cytometric method utilizing monoclonal CD (cluster designation) markers. The device includes accessory CD markers.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA document entitled "Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA."

[67 FR 1607, Jan. 14, 2002]

§ 864.5240 Automated blood cell diluting apparatus.

(a) *Identification.* An automated blood cell diluting apparatus is a fully automated or semi-automated device used to make appropriate dilutions of a blood sample for further testing.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9.

[45 FR 60596, Sept. 12, 1980, as amended at 65 FR 2310, Jan. 14, 2000]

§ 864.5260 Automated cell-locating device.

(a) *Identification.* An automated cell-locating device is a device used to locate blood cells on a peripheral blood smear, allowing the operator to identify and classify each cell according to type. (Peripheral blood is blood circulating in one of the body's extremities, such as the arm.)